

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION**

HEALTHIER CHOICES  
MANAGEMENT CORP.,

Plaintiff,

v.

PHILIP MORRIS USA, INC. and PHILIP  
MORRIS PRODUCTS S.A.,

Defendants.

Case No. 1:20-cv-04816-TCB

**DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THEIR  
MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(6)**

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## I. INTRODUCTION

In their Memorandum in Support of Their Motion To Dismiss Under Fed. R. Civ. P. 12(b)(6) (Doc. 31-1, “Opening Brief”), Defendants<sup>1</sup> explained that HCMC’s Complaint should be dismissed because it is premised on a wholly implausible allegation—*i.e.*, combustion occurs in IQOS devices specifically engineered to make combustion impossible—that is contradicted by the sole evidence Plaintiff relies on to support it. For that reason, under well-settled Supreme Court, 11th Circuit, and Federal Circuit law, the Complaint is implausible on its face and should be dismissed.

HCMC’s opposition (Doc. 36) does not meaningfully address any of this. Instead—in a brief laden with misstatements of the law concerning the relevant pleading standards and mischaracterizations of Defendants’ arguments—HCMC hides behind the procedural posture and a non-existent claim construction dispute in an attempt to convince the Court to let its case get to discovery. The Court should decline imposing that burden on the parties. HCMC’s deficient infringement theory requires the Court to make unreasonable inferences and ignore unambiguous statements in the *very evidence HCMC proffered*. HCMC cannot prevail on the

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<sup>1</sup> All terms defined in Defendants’ Opening Brief have the same meaning herein.

merits, and it should not be given the opportunity to use the judicial process as leverage to extract a nuisance settlement. This case should end now.

## II. HCMC’S STRAINED DEFENSE OF ITS DIRECT INFRINGEMENT CLAIM ONLY CONFIRMS ITS IMPLAUSIBILITY

HCMC does not and cannot contest the central point of Defendant’s Opening Brief—that the MRTPA attached as Exhibit J to Plaintiff’s Complaint directly refutes the conclusory combustion allegations in the Complaint by repeatedly and unambiguously stating that combustion (i) does not, and (ii) cannot occur in the accused IQOS device. *See, e.g.*, Doc. 1-10 (“Ex. J”) at 19 (“***No combustion takes place in THS...***”)<sup>2</sup>; 20 (“THS generates a nicotine-containing aerosol by heating the tobacco in a manner that ***avoids combustion.***”); 23 (“The ***tobacco neither ignites nor burns...*** THS heats tobacco to ***temperatures below the level of combustion...***”); 40 (“The highest observed temperature of the tobacco in the Tobacco Stick is approximately 300°C (measured 0.2 mm from the heater blade) and ***cannot exceed 350°C (the programmed maximum temperature of the heater)*** (Figure 9). This is ***well below the temperature required for tobacco combustion...***”); 41 (“***Since combustion does not occur***, the structural integrity of the Tobacco Stick is retained

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<sup>2</sup> Emphasis added unless otherwise noted.

after use. The tobacco is not consumed, as it is in a cigarette, and no ash is formed.”).<sup>3</sup>

HCMC likewise does not and cannot contest that, under controlling authority, the content of exhibits attached to a complaint supersedes the complaint’s conclusory allegations for purposes of determining the plausibility of HCMC’s claim. *See, e.g., F.T.C. v. AbbVie Prods. LLC*, 713 F.3d 54, 63 (11th Cir. 2013) (courts must “treat specific facts demonstrated by exhibits as overriding more generalized or conclusory statements in the complaint itself”); *Griffin Indus., Inc. v. Irvin*, 496 F.3d 1189, 1206 (11th Cir. 2007) (“[W]hen the exhibits contradict the general and conclusory allegations of the pleading, ***the exhibits govern.***”); *Associated Builders, Inc. v. Alabama Power Co.*, 505 F.2d 97, 100 (5th Cir. 1974) (“If the appended document, to be treated as part of the complaint for all purposes under Rule 10(c), Fed. R. Civ.P., reveals facts which foreclose recovery as a matter of law, dismissal is appropriate.”).<sup>4</sup> Instead, HCMC attempts to manufacture ambiguity on the law and the facts where none exists.

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<sup>3</sup> For the convenience of the Court, citations to documents that are already paginated (e.g., Exhibit J and the FDA Scientific Review) use the pagination of the document itself.

<sup>4</sup> HCMC’s half-hearted, difficult-to-comprehend, attempt to distinguish *Griffin* fails. Doc. 36 at 12 n.2. It appears that HCMC contends that *Griffin*’s holding is limited

### A. HCMC Relies On Outdated Pleading Standards And Bad Law

While playing lip service to *Twombly* and *Iqbal*—which indisputably control—HCMC cites *Auburn Univ. v. IBM*, 864 F. Supp. 2d 1222 (M.D. Ala. 2012) for the proposition that “[t]o state a claim for patent infringement, a plaintiff need only include: ‘1) an allegation of jurisdiction; 2) a statement that the plaintiff owns the patent; 3) a statement that the defendant has been infringing the patent by making, selling, and using [the device] embodying the patent; 4) a statement that the plaintiff has given the defendant notice of its infringement; and 5) a demand for an injunction and damages.’” Doc. 36 at 9 (citing *Auburn*, 864 F. Supp. 2d at 1225). Not so. *Auburn* is bad law and applied the now-**abrogated** pleading standard based

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to judicial or administrative decisions. This is untrue—as the 11th Circuit expressly held, *Griffin* applies generally to all pleading exhibits: “The *Griffin* principle applies if the exhibits ‘plainly show’ that the complaint’s allegations are untrue by providing ‘specific factual details’ that ‘foreclose recovery as a matter of law.’” *Renfro v. Nationstar Mortg., LLC*, 822 F.3d 1241, 1245 (11th Cir. 2016) (citing *Griffin*, 496 F.3d at 1205–06); *see also McElmurray v. Consol. Gov’t of August–Richmond Cnty.*, 501 F.3d 1244, 1251–54 (11th Cir. 2007) (reviewing exhibits attached to the complaint in deciding a facial challenge to subject-matter jurisdiction); *Smith v. Delta Air Lines, Inc.*, 422 F. Supp. 2d 1310, 1324 (N.D. Ga. 2006) (“[c]onclusory allegations and unwarranted deductions of fact are not admitted as true, especially when such conclusions are contradicted by facts disclosed by a document appended to the complaint. If the appended document ... reveals facts which foreclose recovery as a matter of law, dismissal is appropriate.”) (citation omitted). As to HCMC’s apparent argument that Exhibit J does not contradict its pleading, that is deficient for the reasons explained in Defendants’ Opening Brief and herein.



on Form 18 of the Federal Rules. 864 F. Supp. 2d at 1225; *see also Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1335 (N.D. Ga. 2016) (“Rule 84 and its forms, including Form 18, were abrogated in December 2015.”).

The same is true of *In re Bill of Lading*, in which the Federal Circuit expressly differentiated the Form 18 standard for pleading direct infringement in patent cases from *Twombly* and *Iqbal*. *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1334 (Fed. Cir. 2012). Form 18 however, has been gone for years, and cases that rely on it for the proposition that the standard for pleading patent infringement is any different from the standards applicable to all civil litigation are bad law. *See Cont’l Cirs. LLC v. Intel Corp.*, No. CV-16-2026-PHX-DGC, 2017 WL 679116, at \*4 (D. Ariz. Feb. 21, 2017) (“The Court joins the many other cases which have looked to *Iqbal* and *Twombly* for infringement pleading standards after December 1, 2015. **Decisions based on Form 18 are no longer good law.**”); *Peralta v. Cal. Franchise Tax Bd.*, 673 F. App’x 975, 980 n.2 (Fed. Cir. 2016) (“The revised Federal Rules of Civil Procedure entered into effect on December 1, 2015. The revised Rules eliminate Rule 84, which had allowed for patent infringement claims to be plead at a lower standard in form pleadings than that espoused in *Twombly*.”).

A second error of law pervades HCMC’s opposition—the notion that, in order to prevail on their motion to dismiss, Defendants must establish to a metaphysical certainty that there is no factual scenario in which combustion can ever occur. *See, e.g.*, Doc. 36 at 20 (suggesting that Defendants bear the burden of showing that IQOS “cannot...initiate a combustion reaction”).<sup>5</sup> This is nothing more than a thinly veiled attempt to resurrect the “no-set-of-facts” test for pleading sufficiency from *Conley v. Gibson* 355 U.S. 41 (1957) that the Supreme Court expressly overturned in *Twombly*. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 562–63 (2007) (holding that “*Conley’s* ‘no set of facts’ language has been questioned, criticized, and explained away long enough” and “has earned its retirement”); *Ashcroft v. Iqbal*, 556 U.S. 662, 670 (2009) (endorsing “that *Twombly* retired the *Conley* no-set-of-facts test”).

In sharp contrast to the “no-set-of-facts” test of *Conley*, *Twombly* and *Iqbal* not only contemplate but **require** dismissal of complaints that “do not permit the court to infer more than the mere possibility of misconduct.” *Iqbal*, 556 U.S. at 678-

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<sup>5</sup> Even if Defendants bore the burden to show that IQOS cannot initiate a combustion reaction, they have met it because that is precisely what Exhibit J demonstrates: IQOS is designed so that it can **never** reach the temperature that is required for combustion. *See* Doc. 1-10 at 40 (“The highest observed temperature of the tobacco in the Tobacco Stick is approximately 300°C (measured 0.2 mm from the heater blade) and **cannot exceed 350°C (the programmed maximum temperature of the heater)** (Figure 9). This is **well below the temperature required for tobacco combustion...**”).

79; *see also Evans v. Ga. Dep't of Behavioral Health & Developmental Disabilities*, No. CV 415-103, 2018 WL 4610630, at \*3 (S.D. Ga. Sept. 25, 2018) (alterations in original) (citation and internal marks omitted) (“Although there is no probability requirement at the pleading stage, ‘something beyond ... mere possibility ... must be alleged.’”); *Twombly*, 550 U.S. at 556. As HCMC’s opposition confirms, such a “mere possibility” of combustion is the most that even HCMC understands the Complaint to convey. That is insufficient as a matter of law.

**B. HCMC’s Unreasonable Characterizations Of The Evidence Establish That Its Claim Is Speculative**

As explained in Defendants’ Opening Brief (*see* Doc. 31-1 at 9-10, 20-21), HCMC’s infringement allegations hang by a single thread—its conclusory assertion that a statement in Exhibit J that “nitrogen oxides (NO<sub>x</sub>) and carbon monoxide (CO), two important combustion markers, were reduced by over 97%” in IQOS aerosol compared to cigarette smoke somehow shows that some combustion must be occurring. *See* Doc. 1, ¶ 46 (quoting Ex. J at 40-41). In its opposition, HCMC characterizes this language from Exhibit J as “admissions in documents Defendants themselves submitted to the FDA which, at best, show that the IQOS® ‘Tobacco Heating System’ (‘IQOS® system’) is 97% combustion-free, thereby admitting that some combustion occurs.” Doc. 36 at 2. This illogical leap—that a 97% *reduction* in gases associated with combustion is tantamount to an “admission” that a minimal

amount of combustion must be occurring, is both central to HCMC's infringement theory as pled in the complaint and precisely the type of unreasonable inference that *Twombly* and *Iqbal* foreclose.

Essential to HCMC's theory is the demonstrably false assumption that there is ***no explanation other than combustion*** for the presence of trace amounts of nitrogen oxide and carbon monoxide. Defendants explained in their Opening Brief that nothing could be further from the truth. Doc. 31-1 at 20-21. Plaintiff's Exhibit J itself disproves that theory by showing that detected levels of these compounds were almost indistinguishable from the levels present in ambient air (Ex. J at 43-44),<sup>6</sup> and the FDA's Scientific Review showed that any "small differences in the level of nitrogen oxides between the nitrogen atmosphere and synthetic air suggest that the nitrogen oxides are formed mainly by nitrate decomposition and ***not by combustion.***" Doc 31-2 ("FDA Scientific Review") at 21.<sup>7</sup> In other words, the 97%

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<sup>6</sup> See also Ex. J at 42 ("In conclusion there is ***convincing evidence that no combustion occurs*** in [IQOS].").

<sup>7</sup> HCMC's opposition alternates between arguing that the FDA Scientific Review is not subject to judicial notice, and relying on it as evidence that there is some uncertainty about whether combustion occurs in IQOS. Compare Doc. 36 at 18 ("Defendants' reliance on the FDA Scientific Review pursuant to judicial notice is improper.") with *id.* at 20 ("the FDA Scientific Review neither provides a definition

reduction in gases associated with combustion occurs because there is “*no* combustion.” *See, e.g.*, Ex. J at 40. HCMC’s entire infringement theory relies on contorting a single sentence—in a document that repeatedly, expressly, concludes that combustion does not/cannot occur, and that both the authors of Exhibit J and the FDA itself interpreted as evidence confirming that no combustion occurs—into evidence that combustion somehow plausibly does occur. HCMC’s inference is implausible; *Twombly* and *Iqbal* conclusively establish that the Court need not follow HCMC down that rabbit hole.

In *Twombly*, the Supreme Court rejected as deficient allegations that were “consistent with conspiracy, but just as much in line with a wide swath of”

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for the term ‘combustion’ nor concludes that the IQOS<sup>®</sup> system cannot and does not initiate a combustion reaction”). Neither argument is availing.

First, Judicial notice of public government records—including for purposes of evaluating their contents—is plainly permissible. *See Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1280 (11th Cir. 1999) (“For the foregoing reasons, we hold that the district court was authorized at the motion to dismiss stage to take judicial notice of relevant public documents required to be filed with the SEC, and actually filed, for the purpose of determining what statements the documents contain.”).

Second, the plain text of the FDA Scientific Review refutes HCMC’s argument that its findings are anything other than unequivocal: “After conducting a thorough assessment of the scientific evidence, I find that ‘the IQOS system heats tobacco but does not burn it.’” FDA Scientific Review at 11.

innocuous, non-actionable explanations. *Twombly*, 550 U.S. at 554. According to the Supreme Court, the presence of “an obvious alternative explanation” rendered plaintiff’s liability theory implausible. *Id.* at 567. Similarly, in *Iqbal* the Supreme Court found that because there were “obvious alternative explanations” for the inference Plaintiff advocated, the interpretation it sought was “not a plausible conclusion.” 556 U.S. at 682 (citation omitted).

Those rulings require dismissal here. The pleadings (including the Complaint’s attachments) establish that (i) there are multiple “obvious alternative explanations” for the presence of the trace gases that Plaintiff’s infringement theory hinges upon (*e.g.*, they exist in the ambient atmosphere and can be produced by non-combustive heating); and (ii) Plaintiff’s proffered theory is “not a plausible conclusion.” Indeed, the FDA’s professional scientific advisor already examined this issue and expressly stated that “[a]fter conducting a thorough assessment of the scientific evidence, I find that ‘the IQOS system heats tobacco but does not burn it.’” FDA Scientific Review at 11. The notion that the Complaint includes “enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal [conduct]” is fanciful. *Twombly*, 550 U.S. at 556; *see also Stabb v. GMAC Mortg., LLC*, 579 F. App’x 706, 708 (11th Cir. 2014) (*per curiam*) (“To state a plausible claim for relief, a plaintiff must go beyond merely pleading the ‘sheer possibility’ of

unlawful activity by a defendant and so must offer ‘factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.’”) (citations omitted).

HCMC’s pleading lacks the “factual content”—as opposed to conclusory allegations—that would permit a court “to draw the *reasonable* inference” that Defendants are liable for infringement. *Iqbal*, 556 U.S. at 663. Consequently, the Complaint should be dismissed.

### **III. HCMC’S CLAIM CONSTRUCTION ARGUMENT IS A RED HERRING—HCMC HAS FAILED TO IDENTIFY AN ACTUAL CLAIM CONSTRUCTION DISPUTE**

An essential ingredient is missing from HCMC’s repeated but vague assertions about an alleged claim construction dispute regarding the meaning of “combustion”—*any actual disagreement as to what “combustion” means*. Nowhere in its brief does HCMC propose a construction for “combustion” or describe how its proposed construction would impact the issues before the Court. This omission is fatal to the opposition and dispenses with any notion that claim construction provides a basis to deny Defendants’ motion. *See Tridia Corp. v. Sauce Labs, Inc.*, No. 1:15-CV-02284-LMM, 2016 WL4007674 (N.D. Ga. July 14, 2016) (finding it unnecessary to formally construe the claim limitation to grant Defendant’s motion to dismiss, and noting that Plaintiff failed to explain how claim construction

would affect the analysis); *Valentine Commc'ns, LLC v. Six Continents Hotels, Inc.*, 389 F. Supp. 3d 1223, 1233 (N.D. Ga. 2019) (same).

It is no surprise that HCMC failed to propose any alternate construction—it cannot reasonably do so. As explained in Defendants' Opening Brief, the '170 patent defines “combustion reaction” consistent with its plain meaning—heating to a temperature that causes ignition and burning. *See* Doc. 31-1 at 8. Accordingly, the Court need only look to the four corners of the patent to understand the term; a separate claim construction process is unnecessary. *See Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1358 (Fed. Cir. 2001) (“If the district court considers one issue to be dispositive, the court may cut to the heart of the matter . . . District courts have wide latitude in how they conduct the proceedings before them, and there is nothing unique about claim construction that requires the court to proceed according to any particular protocol. As long as the trial court construes the claims to the extent necessary to determine whether the accused device infringes, the court may approach the task in any way that it deems best.”); *see also Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1339 (Fed. Cir. 2013) (claim construction may not always be necessary on motion to dismiss).<sup>8</sup>

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<sup>8</sup> HCMC's reliance on *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337 (Fed. Cir. 2018) is misplaced. In *Nalco*, the plaintiff presented multiple plausible theories of



Contrary to HCMC’s assertion that “Defendants attempt to impermissibly rely on the FDA Scientific Review to advance a construction for the term ‘combustion’ that is unquestionably disputed” (Doc. 36 at 2), Defendants advance no construction from that document. There is no inconsistency between the use of the term “combustion” in the ’170 patent and in Exhibit J and the FDA Scientific Review (in which the FDA validated Exhibit J’s statements). HCMC mischaracterizes Defendants’ brief by claiming it relies principally on the FDA Scientific Review. (See Doc. 36 at 17.) In fact, Defendants’ brief focuses on Exhibit J—the only document that Plaintiff attached to its Complaint to support its conclusory allegation that combustion occurs. Doc. 31-1 at 10-12 (explaining how Exhibit J repeatedly states that combustion does not occur); *id.* at 16-19 (same). HCMC should not be allowed to run from the use of “combustion” in Exhibit J, given that HCMC not only attached it to the Complaint but relied on Exhibit J’s reference to “**combustion** markers” to support its deficient allegation that IQOS meets the “combustion”

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infringement and the defendant’s non-infringement arguments were complex and fact-intensive. *See id.* at 1350 (“[T]hese disputes between the parties hinge on where ‘flue gas’ may be located within the power plant and what limitations are appropriate on where ‘injecting’ may occur.”). And there was no contention in *Nalco* that the evidence Plaintiff attached to its complaint rendered its infringement theory implausible. *Nalco* is inapposite.

limitations of the '170 patent. In any event, as explained in the Opening Brief, Exhibit J and the FDA Scientific Review use the term “combustion” in the same way that the '170 patent does—to refer to ignition or burning. *See* Ex. J at 23 (“The tobacco neither *ignites nor burns*...THS heats tobacco to temperatures *below the level of combustion*...”).

In sum, HCMC’s claim construction “dispute” is nothing of the sort—there is no disagreement between the parties regarding the meaning of the term “combustion,” and no discrepancy between its usage in the '170 patent and the documents that confirm the baselessness of HCMC’s infringement claim.

#### **IV. HCMC FAILS TO SUFFICIENTLY PLEAD INDIRECT PATENT INFRINGEMENT**

First, HCMC’s indirect infringement claims should be dismissed because HCMC has not plausibly pled direct infringement, as explained in the Opening Brief and above. Second, HCMC’s opposition does nothing to meaningfully rebut Defendants’ independent arguments for dismissal of HCMC’s indirect infringement allegations. Indeed, HCMC does little more than restate the deficient allegations in the Complaint. Doc. 36 at 15-16. HCMC points to no factual allegation in its Complaint that supports a plausible inference Defendants knew of the '170 patent before the Complaint; it cannot do so because there are none. Its indirect infringement claims thus fail as a matter of law.

**V. DISMISSAL SHOULD BE WITH PREJUDICE**

As explained in Defendants' Opening Brief, "no amount of amendments or repleading can change the fact that no combustion occurs in IQOS." Doc. 31-1 at 24. Dismissal of the Complaint should be with prejudice.

**VI. CONCLUSION**

Defendants respectfully request that the Court grant Defendants' Rule 12(b)(6) Motion and dismiss Plaintiff's Complaint with prejudice.

Dated: April 16, 2021

Respectfully Submitted,

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**7.1(D) CERTIFICATION**

Counsel for the Defendant Philip Morris USA, Inc. hereby certifies that this document has been prepared with one of the font and point selections approved by the Court in Local Rule 5.1(C).

/s/ Charles A. Pannell, III

Charles A. Pannell, III

**CERTIFICATE OF SERVICE**

I hereby certify that on April 16, 2021, a copy of the foregoing was filed with the Clerk of Court using CM/ECF which will send electronic notification of such filing to all counsel of record.

/s/ Charles A. Pannell, III

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*Counsel for Defendant Philip Morris USA, Inc.*